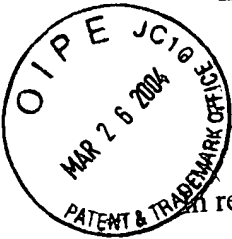


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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

in re application of:

Cynthia B. Robinson, *et al.*

Application No. 10/698,080

Filed: October 29, 2003

For: COMBINATION OF
DEHYDROEPIANDROSTERONE OR
DEHYDROEPIANDROSTERONE-
SULFATE WITH A LIPOXYGENASE
INHIBITOR FOR TREATMENT OF
ASTHMA OR CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Art Unit: 1624

Examiner: Not Yet Assigned

Confirmation No.: 9176

Atty. Docket: 05882.0070.NPUS01

Information Disclosure Statement

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- ☐ 1. This Information Disclosure Statement is being filed;
 - ☐ a. Within three months of the U.S. filing date of a national application other than a continued prosecution application under §1.53(d);
 - ☐ b. Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
 - ☐ c. Before the mailing date of a first Office Action on the merits;
 - ☐ d. Before the mailing of a first Office Action after filing of a request for continued examination under § 1.115.

No statement under 37 C.F.R. § 1.97(e) or fee is required.

or;

- ☐ 2. This Information Disclosure Statement is being filed after the period specified in paragraph 1(a)-1(d) above, but before the mailing date of a Final Rejection or Notice of Allowance, or action that otherwise closes prosecution in the application, and
 - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
 - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent

office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2), or

- ☐ c. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but on or before payment of the Issue Fee. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(i), and
 - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
 - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.

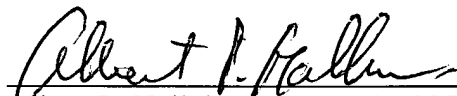
- ☐ 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. _____, filed _____, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.
- ☐ 8. Copies of the documents were cited by or submitted to the Office in Application No. _____, filed _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 08-3038 referencing docket number 05882.0070.NPUS01.

Respectfully submitted,

Date: March 26, 2004


Albert P. Halluin (Reg. No. 25,227)
Robin C. Chiang (Reg. No. 46,619)

HOWREY SIMON ARNOLD & WHITE, LLP
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(Use several sheets if necessary)

ATTY. DOCKET NO.

APPLICATION NO.

APPLICANT

FILING DATE

GROUP

1624

U.S. PATENT DOCUMENTS								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	1.	4,393,066	Jul. 1983	Garrett et al.				
	2.	4,499,064	Feb. 1985	Shive				
	3.	4,575,498	Mar. 1986	Holmes et al.				
	4.	4,628,052	Dec. 1986	Peat				
	5.	4,873,259	Oct. 1989	Summers Jr. et al.				
	6.	4,920,115	Apr. 1990	Nestler et al.				
	7.	4,931,441	Jun. 1990	Lawrence				
	8.	4,985,443	Jan. 1991	Montes				
	9.	5,021,417	Jun. 1991	Prost				
	10.	5,059,595	Oct. 1991	Le Grazie				
	11.	5,077,284	Dec. 1991	Loria et al.				
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	22.	5,489,581	Feb. 1996	Daynes et al.				
	23.	5,527,789	Jun. 1996	Nyce				

Doc. #8012518-v1

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	APPLICANT Cynthia B. Robinson, et al.	
	FILING DATE October 29, 2003	GROUP 1624

	24.	5,532,230	Jul. 1996	Daynes et al.				
	25.	5,538,734	Jul. 1996	Le Grazie				
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	27.	5,629,337	Mar. 1997	Gray				
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	30.	5,686,438	Nov. 1997	Daynes et al.				
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	32.	5,767,278	Jun. 1998	Gaeta et al.				
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	37.	6,087,351	Jul. 2000	Nyce				
	38.	6,093,706	Jul. 2000	Zeligs				
	39.	2002/0042401	Apr. 2002	Ferguson et al.				
	40.	2003/0013772	Jan. 2003	Murphy et al.				
	41.	2003/0138434	Jul. 2003	Campbell et al.				
	42.	2003/0139331	Jul. 2003	Martin et al.				

FOREIGN PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
*	43.	EP 0 279263 B1		Europe				
*	44.	WO 93/16704		PCT				
*	45.	WO 96/16680		PCT				
*	46.	WO 97/48367		PCT				

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no received

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	APPLICANT Cynthia B. Robinson, et al.	
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*	48.	WO 00/54763		PCT				
*	49.	WO 01/015745		PCT				
*	50.	WO 02/069955		PCT				
*	51.	WO 02/85296		PCT				
*	52.	WO 03/072572		PCT				
*	53.	WO 04/014993 A2		PCT				
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*	54.	Araneo <i>et al.</i> , "Dehydroepiandrosterone Reduces Progressive Dermal Ischemia Caused by Thermal Injury", <i>J. Surg. Res.</i> 59(2):250-62 (1995).						
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

LIST OF REFERENCES CITED BY APPLICANT <i>(Use several sheets if necessary)</i> PTO FORM 1449	ATTY. DOCKET NO.	APPLICATION NO.
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65.	Hampl <i>et al.</i> , "Dehydroepiandrosterone sulphate reduces chronic hypoxic pulmonary hypertension in rats," <i>J. Eur. Respir.</i> 21:862-5 (2003).
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77.	Reed, "Aerosol Steroids as Primary Treatment of Mild Asthma", <i>New England J. Med.</i> , 325(6):425-6 (1991).
78.	Rowe <i>et al.</i> , "Effectiveness of Steroid Therapy in Acute Exacerbations of Asthma: A Meta-analysis", <i>Amer. J. Emergency Med.</i> , 10(4):301-10 (1992).
79.	Sasaki <i>et al.</i> , "Cervical Ripening with Dehydroepiandrosterone Sulphate", <i>Br. J. Obstet. Gynaecol.</i> 89(3):195-8, (1982).

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<p align="center">LIST OF REFERENCES CITED BY APPLICANT <i>(Use several sheets if necessary)</i></p> <p align="center">PTO FORM 1449</p>	ATTY. DOCKET NO. 02486.0070.NPUS01	APPLICATION NO. 10/698,080
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80.	Sciarra <i>et al.</i> , "Aerosols", Remington's Pharmaceutical Sciences, 18 th ed. (1990), Eds. Gennaro <i>et al.</i> , pp. 1873-5 and 1694-1712.
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83.	Sonka <i>et al.</i> , "Gout and Dehydroepiandrosterone: 3. DHEA Administration", <i>Endokrynologia Polska</i> 24(3):209-18 (1973).
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